DEC 3 2012

ORTHOFIX

510(k) Summary

Submitter:
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3451 Plano Parkway
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Contact:
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Date Prepared:
September 20, 2012

Prepared By:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800 (phone)

Product Code(s):
NKB; MNI; MNH

Classification Name:
Pedicle Screw Spinal System

Device Class:
Class III Preamendment Device, 888.3070 – *Pedicle screw spinal system* - *Class III Summary and Certification Required

Classification Panel:
Orthopedics

Proprietary Name:
Firebird Spinal Fixation System
Phoenix MIS Spinal Fixation System

Device Description:
The Firebird Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The components include rods, screws, screw bodies, offset head, lateral offsets, and connectors. The system is attached to the vertebral body by means of screws to the non-cervical spine. The spinal construct is completed by

connecting the screws with titanium alloy or cobalt chrome rods.

The Phoenix MIS Spinal Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Indications For Use:

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and
- failed previous fusion

The Firebird Spinal Fixation System components are used with certain components of the Blackstone SFS system, including rods, rod connectors and cross-connectors.

The Phoenix MIS Spinal Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Materials:

Titanium alloy per ASTM F136 and Cobalt-Chrome per ASTM F1537.

Predicate Devices:

The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are substantially equivalent to the previously cleared Firebird Spinal Fixation System (K081684, K082797, K092624, K100044).

Substantial Equivalence: FEA simulation was performed on the worst case subject Firebird Spinal Fixation System and predicate Firebird Spinal Fixation System.

Conclusion: The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System were shown to be substantially equivalent to previously cleared devices with respect to intended use, design, function, materials, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 3, 2012

Orthofix, Incorporated
% Ms. Jacki Geren
Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K122901
Trade/Device Name: Firebird Spinal Fixation System
Regulatory Number: 21 CFR 888.3070
Regulatory Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: September 20, 2012
Received: September 21, 2012

Dear Ms. Geren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K122901:

Device Name: **Firebird Spinal Fixation System**
Phoenix MIS Spinal Fixation System

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

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- tumor,
- pseudoarthrosis, and
- failed previous fusion

The Firebird Spinal Fixation System components are used with certain components of the Blackstone SFS system, including rods, rod connectors and cross-connectors.

The Phoenix MIS Spinal Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Deice Evaluation (ODE)

Ronald P. Jean

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122901